REMARKS

The claims were amended to recite that the soft aliphatic polyurethane is a polyether polyurethane and the hard aliphatic polyurethane can be polyether or polycarbonate. (The basis of this amendment can be found in Paragraph 0004 of the Specification). These two types of polyurethanes are biostable and biocompatible, as required by the claims. This excludes polyester type polyurethanes as they are not biostable. The body will attack polyester polyurethanes, thus they are not suitable for biostable applications.

The claims were rejected under 35 U.S.C. §103(a) as being obvious over Vaillancourt (U.S. 4,798,597) alone or in view of Kitou et al. (U.S. 5,993,436). The rejection is respectfully traversed below, and the Examiner is requested to reconsider and allow the amended claims.

The reference Kitou teaches an indwelling catheter having a single layer tube which can have stripes of x-ray opaque agent embedded in the tube. Applicants' claims recite the multi-layer tube "consisting essentially of" a soft layer and a hard layer. Applicants' claims exclude placing the strips of x-ray opaque agent in the tube as taught by Kitou. The tube of Kitou has a single layer of hard polyurethane which would not accomplish the objective of the present application, which is to make a tube that is flexible, while not being tacky and not having optical defects. The multi-layer tube claimed by Applicants accomplishes this objective, while maintaining biocompatibility and biostable properties.

The reference Vaillancourt teaches a two layer tube which has a soft outer layer (60A-80A hardness) and an even softer inner layer. Although Vaillancourt does not say what the hardness is for his inner layer, he does say that the total tube has less stiffness than a 50A hardness on a comparison basis (see col. 2, lines 48-56). If Vaillancourt's outer layer has a hardness of 60A-80A (as stated at col. 2, line 41), and the total tube behaves as a tube having less than 50A hardness, then the inner layer must be less than 50A hardness and more likely is 40A or less. Vaillancourt's inner layer is thicker than his outer layer (col. 2, lines 66-67). About the only similarity is that both are multi-layer tubes. Vaillancourt has one layer of a soft polyether polyurethane (60A-80A) and a second layer of an even softer layer. Applicants' tube has a soft layer (40A to 95A) and a hard layer (95A to 85D if polyether and 70A to 80D if polycarbonate).

There is no motivation for one skilled in the art to combine the teachings of Vaillancourt and Kitou to arrive at the present invention. Kitou is making a catheter which must be stiff to avoid bending when inserted in the body. Vaillancourt is making a tube with the stiffness of a "wet noodle", as stated by Vaillancourt. To arrive at Applicants invention one would have to use the outer layer of Vaillancourt as the soft layer in the present invention and use the polyurethane of Kitou, absent the x-ray opaque strips, as the hard layer in the present invention. One would also have to have the motivation to consider a single-layer catheter when attempting to make a tube. For one skilled in the art of making medical tubing, that is biocompatible and biostable, this is quite a stretch of combining references and would only be considered in hindsight after being aware of Applicants' invention.

AS TO THE DEPENDENT CLAIMS

Applicants' dependent claims are even further removed from the references Vaillancourt and Kitou. Claim 7 recites a tube where the hard layer is on the inside of the tube, pointing away from Vaillancourt, where the softer layer is on the inside of the tube. Also, claim 8 recites a three layer tube, where the hard layer is both the inside and outside layers, with the soft layer between the two hard layers. Such three layer tube is not taught or suggested by Vaillancourt and Kitou. Claim 9 recites a profile tube where the tube can carry two fluids at the same time in separate passages (see Fig. 5 of Applicants' drawings). A profile tube is not suggested by the references, either taken alone or combined.

The thickness of the hard layer as in Applicants' dependent claim 25 is not disclosed by the cited references. The minimum thickness of Vaillancourt's outer layer, which is actually a soft layer is 0.006 inch which is 6 times the thickness of the maximum thickness (0.001 inch) recited in Applicants' claim 25. The wall thickness of Kitou's catheter can be calculated from his examples, with example 1 being typical. In example 1, Kitou makes a catheter having an outside diameter of 0.88 mm and an inner diameter of 0.65. This calculates to a wall thickness of 0.23 mm/2 = 0.115 mm or 0.004 inch. This is 4 times as thick as the maximum thickness of Applicants' hard layer recited in claim 25.

In summary, Applicants' amended claims, such as claim 1, are unobvious over Vaillancourt taken alone or in view of Kitou. There is no motivation to combine Vaillancourt and Kitou and even if both of these references are combined, they do not teach nor suggest the present invention. Applicants' dependent claims are even more removed from the combined teachings of Vaillancourt and Kitou.

The Examiner is respectfully requested to reconsider and allow the amended claims.

Respectfully submitted,

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